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| APPLICATION NO.                        | FILING DATE               | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|---------------------------|----------------------|---------------------|------------------|
| 09/989,796                             | 11/20/2001                | Michael Y. Zhang     | ACSC 59931 (1987D)  | 1816             |
| 24201<br>FULWIDER P                    | 7590 01/05/2007<br>PATTON | EXAMINER             |                     |                  |
| 6060 CENTER DRIVE                      |                           |                      | BUI, VY Q           |                  |
| 10TH FLOOR<br>LOS ANGELE               |                           |                      | ART UNIT            | PAPER NUMBER     |
|  | ,                         | •                    | 3734                |                  |
|  | ·                         |                      |                     |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE |                           | MAIL DATE            | DELIVERY MODE       |                  |
| 3 MONTHS                               |                           | 01/05/2007           | PAPER               |                  |

# Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|   | Application No.  | Applicant(s) |  |  |  |  |
|---|--|--------------|--|--|--|--|
|   | 09/989,796   | ZHANG ET AL. |  |  |  |  |
| Office Action Summary   | Examiner   | Art Unit     |  |  |  |  |
|   | Vy Q. Bui  | 3734         |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |  |              |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |              |  |  |  |  |
| Status  | ·  |              |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on <u>13 October 2006</u> .  |  |              |  |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b) ⊠ This  | is action is <b>FINAL</b> . 2b)⊠ This action is non-final.                 |              |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |  |              |  |  |  |  |
| Disposition of Claims   |  |              |  |  |  |  |
| 4) Claim(s) 26 and 28-37 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) 26 and 28-37 is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and/or election requirement.   |  |              |  |  |  |  |
| Application Papers  |  |              |  |  |  |  |
| 9) The specification is objected to by the Examine  |  |              |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) acce   |  |              |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |  |              |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |  |              |  |  |  |  |
| Priority under 35 U.S.C. § 119  |  |              |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |  |              |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date  | 4) Interview Summary Paper No(s)/Mail Do 5) Notice of Informal P 6) Other: |              |  |  |  |  |

Application/Control Number: 09/989,796

Art Unit: 3734

#### **DETAILED ACTION**

## Specification

The amendment filed 10/13/2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: in claim 1: "a blow-molded inflated volume", "an inflation pressure required to fill the blow-molded inflated volume".

Applicant is required to explain the subject matters to have a support in the specification or cancel the new matter in the reply to this Office Action.

Further, there is no explanation or definition for the limitation of "an inflation pressure required to fill the blow-molded inflated volume" in the specification.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by WANG et al. (5,556,383).

Notice that an inflation pressure required to fill the blow-molded inflated volume is not specified clearly defined, therefore, Wang reference is still applicable to the claimed invention.

Application/Control Number: 09/989,796

Art Unit: 3734

Wang (for example 1 and table 1) discloses a polymeric balloon having a radial shrinkage less than 6% and a length of about 2cm. It appears that the condition for determining the shrinkage percentage in this present invention is not clearly defined in the specification.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30-33, 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over WANG et al. (5,556,383).

As to claims 30-32, WANG (example 1 and table 1) discloses a polymeric balloon having substantial all structural limitation as recited in the claims, except for the axial growth is less than 6% or 10%. However, WANG discloses radial shrinkage less than 6% in a radial direction and the material of the balloon is substantially homogenous, therefore, it would be reasonable to expect the growth percentage in a same order to the radial shrinkage or less than 6% or 10%.

As to claim 33, WANG (example 1 and table 1) discloses a polymeric balloon of pebax (col. 5, lines 51) having substantial all structural limitation as recited in the claims, except for the balloon is made at least in part of a polyurethane. However, pebax and polyurethane are well-known low compliant polymeric materials suitable for manufacturing balloon in a balloon catheter. It would have been obvious to one of ordinary skill in the art at the time of the invention to have polyurethane as a material to make WANG balloon, as this configuration would guarantee a low compliant balloon with low shrinkage percentage.

Page 4

As to claims 36-37, WANG (example 1 and table 1) discloses a polymeric balloon of pebax (col. 5, lines 51) having substantial all structural limitation as recited in the claims, except for the balloon thickness in the range as claimed. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to make WANG balloon having a thickness in the range as recited in the claims for other applications requiring balloons with bigger sizes.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vy Q. Bui

Primary Examiner

Art Unit 3734

12/26/2006